K132102

5 510(k) Summary

Owner's name:	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
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Contact person:	Dr. Heike Gustke

NOV 1 2 2013

Date prepared:	April 16, 2013
Device name:	BeCe CAD Zirkon HT+
Common name:	Powder, porcelain
Classification name:	Porcelain powder for clinical use (21 CFR 872.6660, product code EIH)
Predicate device:	LAVA™ Frame (K011394)

Device Description

BeCe CAD Zirkon HT+ consists of yttria stabilized zirconia and is suitable for the fabrication of dental ceramic restorations. BeCe CAD Zirkon HT+ is available as milling blank and is processed by milling technique.

Indications for use

BeCe CAD Zirkon HT+ is indicated for the fabrication of single crowns and bridgework.

- Fully anatomical crowns and bridges
- Partial-veneered and fully veneered crowns and bridges

- Dentine core crowns and bridges
- Maryland bridges
- Telescopic crowns (primary part)

Milling machines that are compatible with BeCe CAD Zirkon HT+:

- Roeders milling machines (Soltau/Germany)

Comparison to predicate devices

BeCe CAD Zirkon HT+ is substantially equivalent to the predicate device regarding the indications for use, material properties, technical parameters, processing and biocompatibility.

However, there are slight differences between BeCe CAD Zirkon HT+ and predicate device regarding flexural strength, chemical solubility and coefficient of thermal expansion. These slight differences do not adversely affect safety and effectiveness of BeCe CAD Zirkon HT+ compared to the predicate device. In addition, BeCe CAD Zirkon HT+ fulfills the requirements of ISO 6872, ANSI ADA Specification No. 69 and No. 38 as well as ISO 10993-5, ISO 10993-10 and DIN EN ISO 10993-18.

Based on the test results BeCe CAD Zirkon HT+ is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
C/O Dr. Heike Gustke
Regulatory Affairs Manager
Wilhelm-Herbst-Str.1
28359 Bremen
GERMANY

Re: K132102
Trade/Device Name: BeCe CAD Zirkon HT+
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 22, 2013
Received: September 4, 2013

Dear Dr. Gustke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132102

Device Name: BeCe CAD Zirkon HT+

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S. Betz -S

Digitally signed by Robert S. Betz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Robert S. Betz -S, 0.9.2342.19200300.100.1.1=13001172481
Date: 2013.11.08 10:47:30 -05'00'